IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OREXO AB and OREXO US, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 17-205 (CFC)
	)	
ACTAVIS ELIZABETH LLC,	)	
ACTAVIS PHARMA, INC.,	)	
TEVA PHARMACEUTICALS USA, INC.,	)	**REDACTED**
and TEVA PHARMACEUTICAL	)	**PUBLIC VERSION**
INDUSTRIES, LTD.,	)	
	)	
Defendants.	)	

BRIEF IN SUPPORT OF PLAINTIFFS' DAUBERT MOTIONS TO EXCLUDE IRRELEVANT AND UNSUPPORTED OPINIONS OF DRS. PARK, STINCHCOMB, MCDUFF, AND OMIDIAN

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NATURE AND STAGE OF THE PROCEEDINGS

Orexo[1] filed this infringement case on February 28, 2017, asserting that Defendants'[2] products infringe U.S. Patent 8,454,996 ("the '996 patent"). Fact and expert discovery are complete. Trial is scheduled to begin on March 25, 2019.

SUMMARY OF THE ARGUMENT

***Daubert* Motion # 1 (Dr. Park):** [redacted]

[1] Orexo AB and Orexo US, Inc. (collectively "Orexo" or "Plaintiffs").

[2] Actavis Elizabeth LLC, Actavis Pharma, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. (collectively "Defendants").

[redacted]

Daubert Motion # 2 (Dr. Stinchcomb): The Court should exclude Dr. Stinchcomb's opinion that [redacted]

Dr. Stinchcomb's [redacted]

[redacted] Therefore, at a minimum, Defendants' should not be permitted to rely on Dr. Stinchcomb's [redacted] opinions.

Daubert Motion # 3 (Dr. McDuff): The Court should exclude Defendants' damages expert Dr. McDuff's opinions relating to his (1) Primary Apportioned Value Approach ("Primary Approach") and (2) supposed "economic hold up" and design-around cost opinions as legally flawed and unreliable.

Dr. McDuff's Legally Flawed Primary Approach: Contrary to his contention, Dr. McDuff did not follow the Federal Circuit's accepted analytical or income approach when assessing reasonable royalty damages. The Federal Circuit approach subtracts the infringer's usual or acceptable net profit from its anticipated net profit realized from sales of infringing devices. [redacted]

[redacted]

Alleged Economic Hold-Up Value: Dr. McDuff also improperly failed to consider [redacted] in his damages analysis. By doing so, Dr. McDuff ignored settled law. That the analysis involves "hypothetical" negotiation does not entitle Defendants to posit hypothetical facts in place of those that existed at the date of infringement. The costs and profits associated with changing to a non-infringing product have long been recognized to strengthen a patentee's position in a damages analysis. Dr. McDuff's approach contradicts patent damages law, and his opinions on economic hold-up are unreliable, improper, irrelevant, and should be excluded.

Daubert Motion # 4 (Dr. Omidian): The Court should exclude Dr. Omidian's opinions regarding whether Actavis's Products contain buprenorphine [redacted].

[redacted]

Thus Dr. Omidian lacks qualification and his opinions, are unreliable, irrelevant, do not fit the facts of the case, and would confuse or mislead the jury.

LEGAL STANDARD

The party proffering expert testimony must show by a preponderance of the evidence that the testimony is admissible under *Daubert* and Fed. R. Evid. 702. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994). Trial courts must assess "whether the reasoning or methodology underlying the testimony is scientifically valid and [] whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 591-92.

Expert testimony must meet the "qualification, reliability and fit" requirements. *See Furlan v. Schindler Elevator Corp.*, 516 F. App'x 201, 205 (3d Cir. 2013). An expert satisfies the ***qualification*** element only if the expert "possess[es] specialized expertise." *Id.* To be ***reliable***, the opinions must be based on "good grounds," *i.e.*, on the "methods and procedures of science rather than on

subjective belief or unsupported speculation."[3] *Id.* To assess reliability, courts "scrutinize not only the principles and methods used by the expert, but also whether those principles and methods have been properly applied to the facts of the case." Fed. R. Evid. 702 Advisory Committee's Note to 2000 Amendment. An expert's *ipse dixit* statement does not satisfy the reliability element. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). To ***fit*** the issues of the case, the testimony "must be relevant for the purposes of the case and must assist the trier of fact." *Furlan*, 516 F. App'x at 205.

Fed. R. Evid. 702 requires that "expert's testimony be the product of reliable principles and methods applied to sufficient facts or data." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 711 F.3d 1348, 1373 (Fed. Cir. 2013). Where the expert testimony will overwhelm, confuse, or mislead the jury, Fed. R. Evid. 403 supports exclusion as well. *See Paoli*, 35 F.3d at 746.

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[3] "[F]actors to be considered in a *Daubert* admissibility inquiry include: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the nonjudicial uses to which the method has been put." *Oddi v. Ford Motor Co.*, 234 F.3d 136, 156 (3d Cir. 2000).

DAUBERT MOTION # 1 (Dr. Park)

[redacted]

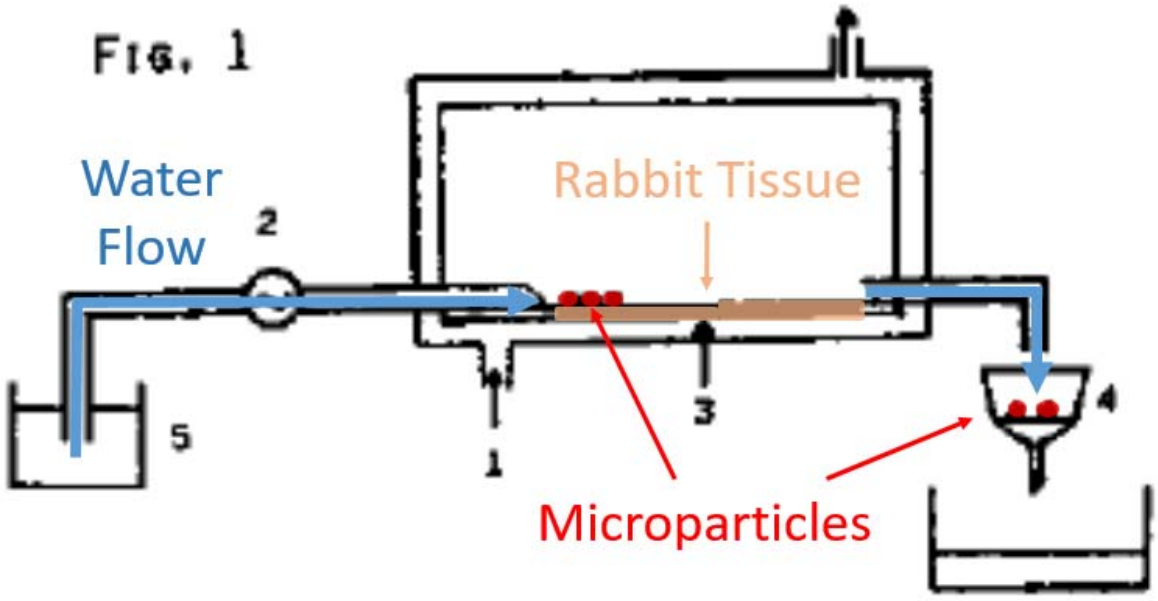
I. DR. PARK [redacted] UNRELIABLE AND IRRELEVANT

Example 4 of the '996 patent uses the "*In Vitro Method to Evaluate Bioadhesion of Microparticles*" developed by Giovanni Sala ("Sala"). (Ex. B, '996 patent, 9:16-57; Ex. A, Sala at 420). The method described in Sala is a flow-through test performed on ***microparticles*** which have been placed on rabbit intestine mucosal tissue. (*See id.*). In the test, the amount of the particles removed from the rabbit mucosa is determined after water is flowed over the mucosal tissue for 10 minutes. (*Id.*). Both Sala and the patent instruct that the test be repeated serially at increasing water flows. (Ex. A, Sala at 421; Ex. B, '996 patent, 9:39-40).

Dr. Park's [redacted]

[redacted]

In both Sala and Example 4, microparticles are placed on rabbit intestinal mucosa and allowed to adhere for two minutes. (*Id.*; Ex. A, Sala at 420). Water is then flowed for 10 minutes and bio/mucoadhesion is assessed by measuring the percentage of active ingredient microparticles detached in the flow and comparing that amount to the total amount of active in the overall formulation. (*Id.*). Figure 1 of Sala below illustrates the setup.



(Ex. A, Sala at 420 (annotations and labels added based on legend for figure)).

[redacted]

[redacted]

Both Sala and Example 4 tested microparticles. (*See* pp. 7, 8). And, in some instances, microparticles themselves may be the finished dosage form, *e.g.*, a powder dosage form (which is encompassed by '996 patent claim 2) or crushed slugs/tablets (in accordance with Sala). [redacted]

Defendants' [redacted] expert, Dr. Donovan [redacted]

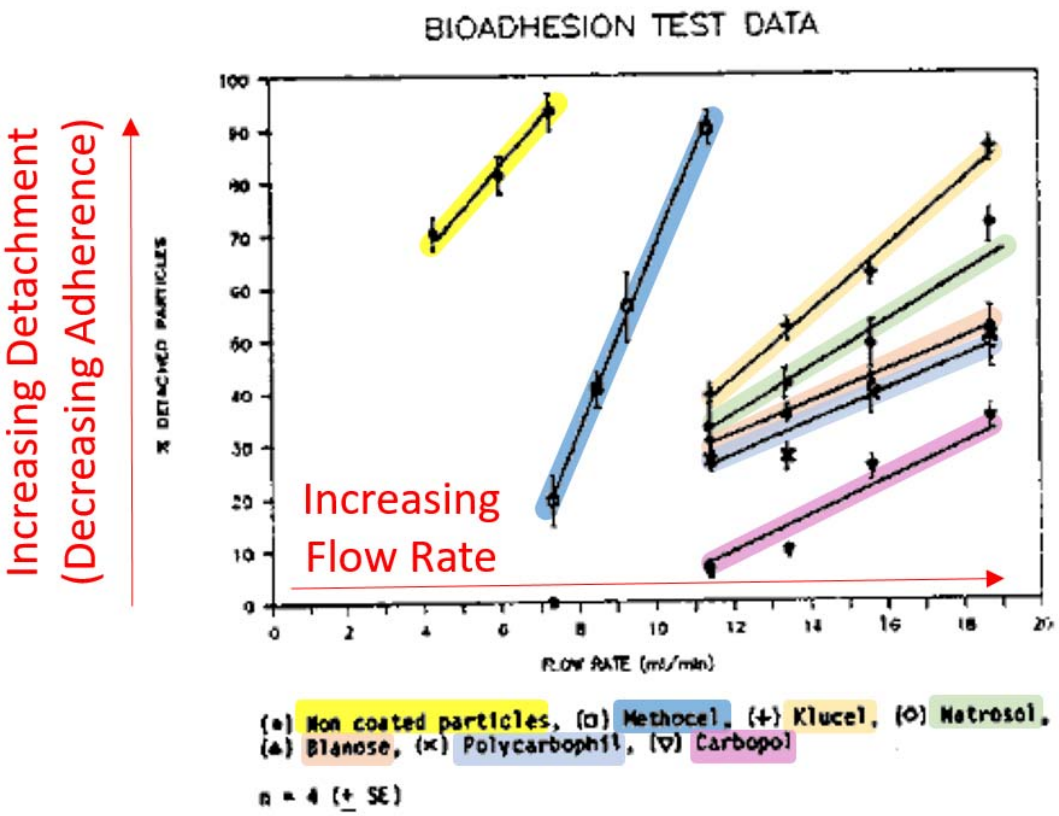
[redacted]

4 [redacted]

[redacted]

[redacted]

FIG. 2



(*Id.* at Figure 2 (annotations added)). The Sala data show that higher flow rates detach more material, and that most of the microparticles of some of the most bioadhesive materials are detached at the highest flow rate tested, about 18 ml/min.

Example 4 instructs that flow tests "are carried out ***using increasing elution flow rates***" (Ex. B, '996 patent 9:39-40), and in the next sentence notes that "[i]f the evaluation is made, the results in Table 2 are seen, where percentages of removal at a high flow rate are listed for: [A-C below]."

A Bio/mucoadhesive mixture according to the invention (Example 1);
B Bio/mucoadhesive mixture according to the invention (Example 2);
C Conventional mixture for rapid dissolution containing no bio/mucoadhesion promoting agent.

TABLE 2

Flow rate	% fentanyl removed		
(ml/min)	A	B	C
>15	<50	<50	>95

(Ex. B, '996 patent 9:43-57 (color annotations added)).

Plainly, "the evaluation to be made" in Example 4 includes tests at increasing flow rates. [redacted]

[redacted]

Sala

makes it clear that freezing may affect the tissue and that testing is necessary to assure no damage. (*See id.*; Ex. A, Sala at 420). [redacted]

To be admissible, "the expert's testimony must 'fit,' in that it must assist the trier of fact." *See Oddi*, 234 F.3d at 145. "Admissibility thus depends in part upon 'the proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case.'" *Id.* [redacted]

II. DR. PARK [redacted] UNRELIABLE AND IRRELEVANT

Dr. Park [redacted]

[5] [redacted]

[redacted]

Example 4 reports the results of exemplary experiments, validated with different flow rates and compared against a control. (Ex. B, '996 patent 9:15-56). It does not provide an absolute standard by which bio/mucoadhesion must be judged regardless [redacted] According to the Court's construction, a bio/mucoadhesive is "A substance that is effective in making the active agent adhere to a mucous membrane or a mucosa (such as in the oral cavity)." (Ex. I, Markman Tr. 57:6-10). And the patent cautions that the examples "show[] preferred but not limiting embodiments." (Ex. B, '996 patent 8:2-3). [redacted]

[redacted]

DAUBERT MOTION # 2 (Dr. Stinchcomb)

Dr. Stinchcomb, [redacted]

I. DR. STINCHCOMB [redacted] UNRELIABLE AND IRRELEVANT

[redacted]

[redacted]

As a

result, her opinion that [redacted] is unreliable, does not fit, and should be excluded. (*See* pp. 7-16; *Oddi*, 234 F.3d at 156).

II. DR. STINCHCOMB [redacted] UNRELIABLE AND IRRELEVANT

[redacted]

[redacted]

III. DR. STINCHCOMB'S [redacted] OPINIONS UNRELIABLE

[redacted]

6 [redacted]

[redacted]

[8] [redacted]

[redacted]

[redacted]

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9 [redacted]

[redacted]

[redacted]

DAUBERT MOTION # 3 (Dr. McDuff)

I. DR. MCDUFF'S DAMAGES [redacted] SHOULD BE EXCLUDED

A. The Federal Circuit's "Analytical Method"

The analytical or income approach is an alternative to the *Georgia-Pacific* "hypothetical negotiation" methodology for assessing reasonable royalty damages in patent cases. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009). [redacted]

[redacted]

Deviations from the Federal Circuit's analytical approach that lack explanation and support from cases or articles should be excluded. *See, e.g.*, *Ultratec, Inc. v. Sorenson Commc'ns, Inc.*, No. 13-cv-346, 2014 WL 5080411, at *4 (W.D. Wis. Oct. 9, 2014) (stating failure to "compare defendants' infringing profits to their noninfringing profits" problematic); *NetAirus Techs., LLC v. Apple, Inc.*, No. CV10-03257, 2013 WL 11237200, at *3-4 (C.D. Cal. Oct. 23, 2013) (excluding testimony "similar to the 'analytical approach'" where the expert "could not identify any cases, textbooks, or articles that followed the approach").

B. Dr. McDuff [redacted]

[redacted]

10 [redacted]

[redacted]

C. Dr. McDuff [redacted]

[redacted]

D. Dr. McDuff's Primary Approach Opinions Are Unreliable [redacted]

Dr. McDuff's Primary Approach calculation differs so substantially from the accepted Federal Circuit approach that it is "plagued by logical deficiencies" and not reliable. *See Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1296 (Fed. Cir. 2015). Dr. McDuff's failure to follow the analytical or income approach is analogous to the excluded expert's approach in *Ultratec*. In *Ultratec*, defendant's expert did not "compare defendants' infringing profits to their noninfringing profits" and instead calculated a subset of defendants' infringement profits, by taking best case profit projections from infringement subtracted by base case profit

projections that also included profits from infringement. 2014 WL 5080411, at *4. ***The Court found that the calculation of "excess profits" yielded a much lower royalty rate*** than would have resulted from considering "the total profits resulting from infringement." *Id*. The Court concluded that, without "information and explanation from defendants as to why [defendant's expert's] profitability method is reliable, [the Court] will not permit him to testify because he will have nothing helpful to offer the jury." *Id*. at *5.

[redacted]

[redacted]

[redacted]

[redacted] At the hypothetical negotiation here, the parties would have recognized "'the opportunity for making substantial profits if the two sides [were] willing to join forces'" by arriving at a license of the technology. *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1304 (Fed. Cir. 2015) (quoting *Gaylord v. United States*, 777 F.3d 1363, 1368 (Fed. Cir. 2015)). [redacted]

II. DR. MCDUFF'S [redacted] OPINIONS SHOULD BE EXCLUDED

[redacted]

[redacted]

The "hypothetical negotiation requires the court to envision the terms of a license agreement reached as the result of a supposed meeting between the patentee and the infringer ***at the time the infringement began***." *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1554 (Fed. Cir. 1995) (emphasis added).

[redacted]

[12] "Standards development organizations publish standards, which are lists of technical requirements . . . [to] ensure[] interoperability among compliant devices." *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1208 (Fed. Cir. 2014). "Because the standard *requires* that devices utilize specific technology, compliant devices *necessarily* infringe certain claims in patents that cover technology incorporated into the standard. These patents are called 'standard essential patents.'" *Id*. at 1209. Organizations require owners of standard essential patents to grant licenses on "reasonable, and nondiscriminatory," terms. *Id*.

[redacted]

"The hypothetical negotiation is hypothetical in the sense that the negotiation itself is imaginary, not in that it allows the parties to construct an entirely imaginary world that ignores the facts as they existed at the date of infringement." *Astrazeneca AB v. Apotex Corp.*, 985 F. Supp. 2d 452, 501 (S.D.N.Y. 2013), *rev'd in part on other grounds*, 782 F.3d 1324 (Fed. Cir. 2015). *Astrazeneca* rejects the very argument that Dr. McDuff makes here:

> Apotex argues that analyzing its negotiating position by reference to the cost and delay associated with developing a non-infringing alternative formulation is improper. Doing so, Apotex says, leads to a royalty rate that is unfairly based on the "hold-up" value of patents rather than their actual economic advantage over alternative, non-infringing approaches. . . . The cases on which Apotex relies . . . deal with the special situation in which a technical standard is set for an industry that puts one patent holder "in a position to 'hold up' industry participants from implementing the standard." . . . ***These considerations***

[redacted]

985 F. Supp. 2d at 500-01 (emphasis added) (citations omitted). Here, the '996 patent is not a standard essential patent and thus, as in *Astrazeneca*, economic hold-up considerations are inapplicable. *See id.; cf. TCL Commc'ns Tech. Holdings, Ltd. v. Telefonaktiebolaget LM Ericsson,* No. CV 15-2370 JVS, 2018 WL 4488286, at *6 (N.D. Cal. Sept. 14, 2018) ("Hold up occurs when a patent holder seeks to extract more for the use of his patent than the value which his patent adds ***to a standard***.") (emphasis added). Accordingly, Dr. McDuff's opinions on this topic should be excluded as unreliable, irrelevant (as they do not fit the facts of the case), and confusing and misleading to a jury.

DAUBERT MOTION # 4 (Dr. Omidian)

I. DR. OMIDIAN [redacted] UNRELIABLE AND INADMISSIBLE *IPSE DIXIT*

Dr. Omidian is not qualified [redacted]

[redacted]

[redacted] Also, his opinions are not based on reliable expert analysis that would assist the jury.

Dr. Omidian [redacted]

[redacted] Raman analysis allows for the identification of components (*e.g.*, buprenorphine) through the collection of spectra which exhibits different spectral features for each component. (*See* Ex. R, Bugay Opening, ¶¶ 39-42, Fig. 2). Raman imaging does not simply measure the spectral response for the compound you are most interested in; rather, it measures the response for all components in the sample. (*See id.* at Fig. 2 [redacted]

[redacted]

II. DR. OMIDIAN APPLIES THE WRONG CLAIM CONSTRUCTION

Dr. Omidian's opinions that Actavis's Products do not meet the "presented at," "adhered to," and "carrier particle" limitations should be excluded because they are belated attempts to construe terms for the jury and improperly read additional requirements into the construction for these terms.

Dr. Omidian [redacted]

[redacted]

Similarly, Dr. Omidian [redacted]

[redacted] And again, Defendants did not seek construction of these terms.

Because Dr. Omidian applies the wrong claim construction, his opinions do not fit the facts of the case, are unreliable and irrelevant, and should be precluded. *See, e.g., Personalized User Model*, 2014 WL 807736, at *1; *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1224 n.2 (Fed. Cir. 2006) (affirming exclusion of testimony of expert based on incorrect claim construction). Also, Dr. Omidian's opinions would only confuse or mislead the jury. *See Changzhou Kaidi Elec. Co. v. Okin Am., Inc.*, No. 13-cv-1798-CCB, 2015 WL 1959404, at *5 (D. Md. Apr. 29, 2015) (barring expert testimony inconsistent with the court's claim construction under Fed. R. Evid. 403).

CONCLUSION

For the above reasons, Orexo respectfully requests this Court to preclude the expert testimony as stated above.

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December 28, 2018

CERTIFICATE OF COMPLIANCE

This brief complies with the type–number limitations set forth in Judge Colm F. Connolly's Rule 16 Scheduling Order for Patent Cases - Revised Nov 14, 2018 because the text is 14-point Times New Roman font and it contains [_**9,119**_] words based on a count made by Microsoft Word, excluding the caption page, table of contents, table of authorities, and signature block.

CERTIFICATE OF SERVICE

I hereby certify that on January 4, 2019, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 4, 2019, upon the following in the manner indicated:

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